

Accelerating Clinical Data Review with Traceable Workflows

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By Revvity Signals

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Introduction

Clinical trials are complex and generate vast quantities of data. With trials often spread over multiple sites, and even multiple countries and continents, effectively managing data review to keep the studies progressing has always been difficult. Today, those challenges continue to grow as the volume of data for trials has expanded to include genomic, proteomic, and transcriptomics data, and increasingly, real-world data derived from sources such as electronic medical records.

While electronic data capture (EDC) tools have made significant inroads to help improve data collection efficiency since their introduction roughly 30 years ago, too many trials still leave a large and inefficient paper trail of spreadsheets and PDFs that hinder decision making. Not having fast and easy access to all your trial data, in close to real time, can present roadblocks to meeting regulatory requirements and shortening drug development timelines.

Today's clinical trials thrive on data, data access, and traceable workflows, elements that are hampered by traditional tools that include static spreadsheets, disparate and disconnected communication tools, and batch-driven data access that only slows down discovering insights from the trial data, complicating true collaboration, and running the risk of introducing compliance errors.

Fortunately, today's clinical trial managers can tap technology-driven solutions that accelerate clinical data review, enable real-time collaboration between colleagues, and improve decision-making by housing all the trial data in one place.

Centralized Data Access

Managing data from multiple trial sites can be an arduous process, but one that is necessary to gain an accurate view of all the data collected and analyze it to gather critical insights on the progress of the trial. Fragmented and siloed data still hamper many clinical trials; with multiple trial sites, data is often housed in disparate systems, managed by different stakeholders, and not uniformly updated on a set schedule. This can result in miscommunication between trial sites and trial managers, data that can't be uniformly analyzed, and time-consuming manual data handling.

Signals Clinical™, from Revvity Signals Software™, solves these issues by serving as a centralized hub that houses all clinical data from all trial sites. Leveraging artificial intelligence (AI) and machine learning (ML) solutions, the solution automates data collection and data mapping. It directly integrates with leading electronic data capture (EDC) solutions from providers such as Medidata and Veeva EDC, to allow real-time access to the most recent trial data, delivering it in a standard format, ready for analysis. Removing the need for manual exports, batched transformations, or time-consuming extract, transform, load (ETL) operations allows trial sponsors to quickly derive insights from their data.

With a centralized data repository, managers across a clinical trial can easily access study data and filter it by different attributes such as demographics, reported adverse events, or clinical endpoints. AI-enabled insights can inform deeper dives into the data to study the effects on patients in a certain age bracket or those who have experienced a negative drug interaction. Because the data is harmonized and up-to-date, team members can act on information based on the current state of the trial, rather than playing catch-up or chasing solutions based on old data. This dynamic feedback loop of real-time data and real-time analysis can provide critical velocity to a clinical study.

Further, because trial data is standardized in a unified data format, drug discovery and development researchers can perform cross-study analyses across a company's entire portfolio of ongoing and past clinical trials—to spot trends or to derive insights from all adverse events across all studies—without the need to build a customized data pipeline for each separate cross-study analysis.



Traceable, Auditable Workflows

Traditionally, clinical review of data has been handled via email, spreadsheets, or static reports, making it hard to keep track of the information. The lack of traceability and auditability made it difficult to adequately provide context for decisions made during regulatory review, exposing a drug sponsor to significant compliance risk.

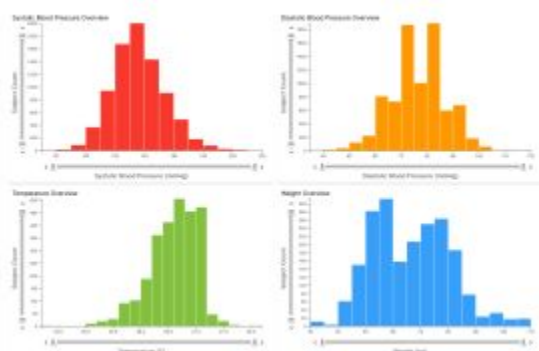
Signals Clinical deftly handles this challenge via its ability to trace every aspect of every data interaction in a clinical trial. Within the solution, users can comment directly on data visualizations, raise and manage queries, assign responsibilities, and resolve issues—all in one

interface. Whether it is annotating a patient profile, querying the data, or flagging an adverse event or safety signal, all interactions are logged comprehensively to capture the use, timestamp, and activity. By doing this, the solution can generate a real-time audit trail of all decision-making related to the trial.

This activity is analogous to the workings of an air traffic control system, where multiple towers coordinate and manage the different parts of an airplane's journey from one airport to the next—from takeoff through cruising altitude, descent, and landing. Likewise, clinical trials involve a range of stakeholders, all tasked with making different decisions on safety, clinical operations, and data management. All must access the shared data, make important decisions, and suggest additional actions, while providing full transparency to other users of their actions.

For instance, if a severe adverse event (AE) such as syncope is detected in a study participant, a medical reviewer can create a causality assessment, flag the event for broader review by the team, and initiate a query, all within the single solution. Users can highlight data anomalies directly in visualizations or tabular listings and raise queries that sync back to the source EDC. This centralization eliminates redundant workflows, such as transcribing issues into separate systems, and fosters faster query resolution. Additionally, because the process includes all team members, from clinical operations to safety reviewers, each action related to the AE is recorded and visible to other members of the team, providing a collaborative environment, with a single truth, whether colleagues are in the next room or a continent away.

So, in a real-world collaboration workflow, a reviewer could mark several out-of-range liver function tests as suspicious, annotate them with potential causality notes, and escalate them for safety review, all without leaving the subject profile. A data manager reviewing the same profile could then raise a formal query to the EDC system with a single click. This seamless collaboration dramatically reduces manual operations, saving time and money, while ensuring that queries and concerns can be tracked through to resolution.



Finally, not all data in a clinical trial should be visible to anyone working on the study. For this reason, Signals Clinical provides role-based permissions, providing each stakeholder access to the right tools and the right data, while ensuring they don't work on issues beyond their purview. Clinical reviewers, data managers, and safety officers can work in parallel while maintaining strict controls on their responsibilities, but with visibility into others' actions.

Advanced Analytic Capabilities

While fostering collaboration, improving workflows, and ensuring data integrity are keys to successfully managing a clinical trial, so too is the ability to apply powerful data analysis tools to the data generated.

Signals Clinical, in concert with the Spotfire® Copilot AI assistant, leverages large language models (LLMs) to allow users to query data and generate charts and graphs—powerful

visualizations that can help unlock data insights. For example, patient timeline views allow users to visualize the temporal relationships between dosing, return of abnormal lab results, adverse events, and other data. The LLM can aid in discerning causality patterns from large buckets of data that might not be possible via manual human review. Population-level dashboards, such as adverse event bar charts or lab parameter scatter plots, can help illuminate outliers or emerging signals that need to be managed. For instance, a user could generate a visualization of a drug's safety profile to examine drug-induced liver injury, mapping ALT versus bilirubin values to normal ranges to readily identify patients falling into Hy's Law quadrant, which can provide a safety signal in a trial.

Further, users querying and investigating data can drill down to the individual patient level. This capability would make it easy to find, for instance, if an episode of hypertension came shortly after a patient was administered an investigational new drug.



Eliminating Bottlenecks via Automation

Traditional methods of data review relied on scheduled data exports, static data cuts, and the time-consuming, labor-intensive task of data cleaning. To ensure researchers and trial managers have access to the most up-to-date data, Signals Clinical automates the entire data pipeline. Revvity Signals holds a patent for a machine-learning-based automated mapping engine. Proof-of-concept studies have demonstrated that this engine maps Electronic Data Capture (EDC) data to the Study Data Tabulation Model (SDTM) more efficiently and accurately than manual methods. With this engine, as soon as data is updated in the EDC, the solution ingests it, maps it to the unified data model, and flags any data that needs amendments or tasks. By eliminating bottlenecks, this automation enables researchers and trial managers to make faster, more informed decisions.

Integration and Collaboration

While many drug sponsors and clinical research organizations (CROs) recognize the value of traceable workflows, Signals Clinical goes much further, solving challenges and delivering insights other systems struggle with, such as:

- **real-time safety monitoring** without waiting on data extracts or reprogramming
- **cross-functional collaboration** where annotations, decisions, and queries are visible and actionable in one place
- **faster query resolution** through integration with EDC systems and in-solution query dashboards
- **regulatory-ready audit trails** that provide clear documentation of who made decisions, why, and when
- **reduced manual processes** related to tracking changes, managing reviews, and preparing reports.

As clinical trials become more data intensive and analytics hungry, it is vital that drug sponsors conducting clinical trials can make fast and accurate decisions based on the most recent data. Signals Clinical has the capability to reengineer how clinical trials teams access and interact with data, while providing a water-tight method of embedding traceability and automation throughout the entire data review process.

In this new environment, centralizing clinical trial data to allow real-time updates and a complete audit trail are not wants; they are must-haves to allow drug sponsors to proactively manage their trials and manage risks, all within an environment that fosters collaboration.

Summary: Streamlining Clinical Data Review with Signals Clinical

Clinical trials generate increasing volumes of diverse data, yet many teams still rely on outdated, siloed tools that slow down decision-making and increase compliance risk. Signals Clinical, from Revvity Signals Software, addresses these challenges by centralizing data, automating data workflows, and enabling traceable, collaborative processes.

By integrating with leading EDC systems, Signals Clinical provides real-time access to harmonized trial data. Built-in AI and ML tools automate data cleaning and mapping, reducing manual tasks and ensuring that researchers are always relying on current data. Powerful analysis and visualization tools—enhanced by large language models—enable users to explore patient timelines, detect safety signals, and generate critical insights.

Signals Clinical helps ensure drug sponsors get full value from the increasingly complex and data-rich clinical trial environment, for faster, better-informed decisions, clearer oversight, and accelerated drug development.

Signals Clinical can transform your clinical data review. [Learn more.](#)



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